

7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: June 5, 1995.

Chuck Clarke,

Regional Administrator.

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#### 40 CFR Part 372

OPPTS-400086A; FRL-4952-71

#### Acetone; Toxic Chemical Release Reporting; Community Right-to-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** EPA is granting a petition to delete acetone from the list of toxic chemicals under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). This deletion is based on a determination that acetone meets the delisting criteria of EPCRA section 313(d)(3). By promulgating this rule, EPA is relieving facilities of their obligation to report releases of acetone that occurred during the 1994 calendar year and releases that will occur in the future. This relief applies only to the reporting requirements under section 313 of EPCRA.

**DATES:** This rule is effective June 16, 1995.

**FOR FURTHER INFORMATION CONTACT:** For specific information on this final rule: Maria J. Doa, Petitions Coordinator, Telephone: 202-260-9592. For more information on EPCRA section 313: Emergency Planning and Community Right-to-Know Hotline: Environmental Protection Agency, Mail Code 5101, 401 M St., SW., Washington, DC 20460, Toll free: 1-800-535-0202, In Virginia and Alaska, 703-412-9877 or Toll free TTD: 1-800-553-7672.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

##### A. Statutory Authority

This final rule is issued under sections 313(d) and (e)(1) of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. 11023. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 (Pub. L. 99-499).

##### B. Background

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using listed toxic chemicals to report their environmental releases of

such chemicals annually. Beginning with the 1991 reporting year, such facilities must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the Pollution Prevention Act (42 U.S.C. 13106). When enacted, section 313 established an initial list of toxic chemicals that was comprised of more than 300 chemicals and 20 chemical categories. Section 313(d) authorizes EPA to add or delete chemicals from the list, and sets forth criteria for these actions. Under section 313(e)(1), any person may petition EPA to add chemicals to or delete chemicals from the list. EPA has added chemicals to and deleted chemicals from the original statutory list. EPA issued a statement of petition policy and guidance in the Federal Register of February 4, 1987 (52 FR 3479), to provide guidance regarding the recommended content and format for petitions. On May 23, 1991 (56 FR 23703), EPA published guidance regarding the recommended content of petitions to delete individual members of section 313 metal compound categories. EPA has also published a statement clarifying its interpretation of the section 313(d)(2) criteria for adding and deleting chemicals from the section 313 toxic chemical list (59 FR 61439, November 30, 1994).

##### II. Description of Petition and Regulatory History

On September 24, 1991, EPA received a petition from Eastman Chemical Company and Hoechst Celanese to delete acetone from the EPCRA section 313 list of toxic chemicals. The petitioners contend that acetone should be deleted from the EPCRA section 313 list because it does not meet any of the EPCRA section 313(d)(2) criteria and because acetone's low photochemical reactivity does not present substantial concerns for formation of tropospheric ozone or other air pollutants.

On September 30, 1994, following a review which consisted of a toxicity evaluation and an exposure analysis, EPA proposed to grant the petition to delete acetone from the section 313 list by issuing a proposed rule in the Federal Register (59 FR 49888). The proposal to grant the petition was based upon EPA's finding that acetone did not meet the listing criteria found in section 313(d)(2) of EPCRA. It was EPA's belief that there was insufficient evidence to demonstrate that acetone causes or can reasonably be anticipated to cause significant adverse human health or environmental effects.

Until this time, acetone has been considered to be a Volatile Organic Compound (VOC). Emissions of VOCs

are managed under regulations (40 CFR parts 51 and 52) that implement Title I of the Clean Air Act (CAA), as amended, 42 U.S.C. 7401 *et seq.* EPA's definition of VOCs excludes certain listed chemicals that have been determined to be negligibly photochemically reactive (57 FR 3941, February 3, 1992). Elsewhere in this issue of the Federal Register, EPA is finalizing its addition of acetone to the list of compounds excluded from the definition of a VOC based on the determination that acetone has a negligible contribution to tropospheric ozone formation.

##### III. Final Rule and Rationale for Delisting

##### A. Comments on the Proposed Deletion of Acetone

The public comment period for the proposed rule closed on November 29, 1994. EPA received 51 comments on the proposed rule to delete acetone. Of these, 29 comments concurred with the proposal, and 22 comments objected to the proposal.

The Chemical Manufacturers Association objected to the statement in the proposed rule that all VOCs "meet the criteria for listing under EPCRA section 313."

In the proposed rule, EPA did not state that all VOCs meet the criteria for listing under EPCRA section 313 solely by virtue of their being so designated. However, EPA reaffirms its position as stated in the proposed rule, that chemicals that clearly fit the definition of VOC under the CAA meet the listing criteria of EPCRA section 313. VOCs contribute to the formation of tropospheric ozone. Ozone can reasonably be anticipated to cause significant adverse effects on human health and the environment, and therefore meets the listing criteria of EPCRA section 313.

Artco Inc. and National Marine Manufacturers Association comment that EPA should further research other chemicals which are not depleting the stratospheric ozone layer and promulgate their removal as well. EPA does not believe that the removal of chemicals from the EPCRA section 313 list is warranted solely on the basis of whether they deplete the stratospheric ozone layer. In making a determination that a chemical should be deleted from the EPCRA section 313 list, EPA examines whether the chemical meets any of the criteria set forth in EPCRA section 313(d)(2). A chemical which is shown not to deplete the stratospheric ozone layer could still meet one of the other criteria, and thus be deleted from the list.

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Eastman Chemical Co. and Hoechst Celanese stated that the deletion of acetone will "improve EPA's TRI program as well as conserve EPA and industry resources." Further, Outboard Marine Corp., Hoechst Celanese, and the Savannah River Pulp and Paper Corp. stated that the removal of acetone from the list of EPCRA section 313 toxic chemicals will reduce, in part, the administrative burden on facilities.

As described in the economic analysis, EPA agrees that the deletion of acetone will result in a resource savings by EPA and industry. In addition, EPA agrees that, as a result of this action, there will be a decrease in the administrative burden on facilities who have previously been required to report for acetone under EPCRA section 313.

A number of the commenters who supported the deletion stated that acetone is a substitute for more hazardous air pollutants, and that removing acetone from the list will encourage facilities to use acetone rather than these more hazardous chemicals. Specifically, Eastman Chemical Co. and Hoechst Celanese commented that the proposed rule does not address any of the environmental benefits associated with deleting acetone from the section 313 list. These two commenters pointed to the benefits derived from the use of acetone as a substitute for other regulated chemicals.

Although there might be environmental benefits from using acetone rather than some other chemicals, this has no impact on whether acetone meets the listing criteria of EPCRA section 313(d)(2). EPA agrees that, to the extent that the substances being substituted by acetone are more hazardous to human health or the environment than acetone, such substitution would be beneficial.

These two commenters further brought up several technical points, which they felt should have been included in the proposal. Specifically, they believe that a description of drinking water studies which have been conducted with acetone, as well as information on the recently revised oral reference dose (RfD) for acetone, would be a useful addition to the preamble to this final rule. EPA acknowledges that the drinking water studies have been conducted, but does not feel that a description of them is warranted. These studies support the decision to delist acetone. EPA also acknowledges that the RfD has recently been revised. At the time of publication of the proposed rule, the RfD was 0.1 milligram per kilogram per day (mg/kg/day). EPA has revised this RfD to 0.9 mg/kg/day. This higher value reflects a slightly lower toxicity

and, as stated above, supports the delisting decision.

A number of the commenters that oppose the delisting stated that there are substantial data to support a concern for health effects from acetone, and that EPA's review of evidence of toxicity for acetone must address the serious concerns raised by the Agency for Toxic Substances and Disease Registry (ATSDR) in its *Draft Toxicological Profile for Acetone*. In addition, as some commenters have pointed out, there are insufficient data to assess the toxicity of acetone.

As reviewed by the ATSDR, there has been considerable research on the health effects of acetone. However, most of this research has involved acute or subchronic exposure to relatively moderate and high levels of acetone. There is a lack of information with which to firmly characterize the critical effects of low-level exposure to acetone. Under EPCRA section 313, a lack of evidence cannot be used as a basis for listing a chemical. The known toxicity levels for acetone fall in the range which can be considered to be moderately low to low, and the decision must be based on the weight of the evidence available.

EPA has reviewed the ATSDR draft profile as well as other relevant materials and has concluded that there is not sufficient evidence of toxicity to retain acetone on the EPCRA section 313 list. According to the ATSDR, based on a lowest observed adverse effect level (LOAEL) of 1,250 parts per million (ppm) for (transient) neurological effects over a 6-week period, intermediate and chronic inhalation Minimal Risk Levels (MRLs) of 13 ppm were calculated. Furthermore, the ATSDR indicates that levels of acetone which are normally found in outdoor air are generally significantly lower than this, at less than 8 parts per billion (ppb), and also generally lower than the air concentrations of acetone inside homes. At this time, there is insufficient evidence regarding chronic or subchronic exposure to such low levels of acetone to warrant listing (Ref. 1).

Several commenters recommended that EPA require industry to fully test acetone for toxicity under the criteria of section 4 of the Toxic Substances Control Act (TSCA), stating that testing should be performed before acetone is removed from the public's right-to-know. Other commenters, noting that EPA is currently negotiating with industrial users of acetone for neurotoxicity testing of the chemical, claimed that the proposal for delisting is ill-timed and inappropriate.

At this time, the Agency has already entered into an Enforceable Consent

Agreement with industry, requiring subchronic testing of acetone for neurotoxicity. At concentrations to which workers may be exposed in the workplace, which are much higher than those in outdoor air, central nervous system (CNS) effects such as narcosis, headache, and changes in operant behavior do appear to be relevant concerns indicative of neurotoxicity. However, the criteria for requiring neurotoxicity testing under TSCA section 4 and the criteria for inclusion in section 313 of EPCRA are very different. At this point in time, the weight of the evidence is not sufficient to show that acetone meets the EPCRA section 313(d)(2) criteria for listing. EPA cannot deny a petition under EPCRA section 313 based on the fact that there is going to be performed to fill data gaps.

A number of commenters stated that EPA should consider the synergistic effects of acetone together with other chemicals and stated that exposure to acetone is well known to increase the toxicity of many other chemicals. Commenters stated that the increase in toxicity of other compounds in combination with exposure to acetone as detailed in the ATSDR draft profile justifies maintaining the EPCRA section 313 listing of acetone.

The ATSDR draft profile does provide a detailed review of the interaction of acetone and other chemicals. This report indicates that acetone may alter the effect of other chemicals by either increasing, decreasing, having a mixed effect on or having no effect on their toxicity. For example, carbon tetrachloride, halogenated alkanes, ethanol, and some ketones were more toxic when co-administered with acetone. However, acetone had mixed effects on the toxicity of other chemicals (dichlorobenzene, chlorinated alkanes, possibly halogenated alkanes, nitrosoamine, and acetonitrile) either varying doses or for different toxicity endpoints. Furthermore, acetone has reported effect on styrene or methyl ethyl ketone; and actually reduced the toxicities of acetaminophen and semicarbazide (Ref. 1).

As with the toxicity of acetone alone, the doses of acetone required for the interactive effects far exceed the concentrations of acetone which are found in outdoor air. For example, the lowest doses for acetone potentiating toxicity reported by the ATSDR were found with carbon tetrachloride. The toxicity of carbon tetrachloride was shown to be potentiated by co-administration of acetone. However, non-effective doses of acetone were high as 78 milligrams/kilogram (mg



twice a day for 3 days, or 1,000 ppm over 4 hours (Ref. 1).

Again, the weight-of-the-evidence for the synergistic effects of acetone on the toxicity of other chemicals is not sufficient to show that acetone meets the EPCRA section 313(d)(2) criteria for listing.

Several commenters state that EPA has not considered the effects of acetone on susceptible populations such as children, the elderly, or pregnant women, as detailed in the ATSDR draft profile. EPA disagrees. The ATSDR draft profile reported no human data on acetone in "more susceptible populations." Several studies in rats reported possible sex differences in susceptibility. Other factors which may have affected susceptibility in rats were age and pregnancy; however, no doses were reported.

The National Council of the Paper Industry for Air and Stream Improvement Inc. submitted a review on the *Toxicity of Acetone* in support of delisting acetone. This report concludes that acetone does cause CNS depression and irritation of mucous membranes, but that these effects become apparent only at high concentrations (above 500 ppm for irritation and 1,000 ppm for CNS effects).

This review was not as detailed as the ATSDR Draft *Toxicological Profile for Acetone*; however, reports of effective dose levels were similar. This review provides further indication of the relatively high levels of acetone necessary to induce toxicity or enhance the toxicity of other chemicals.

The Chesapeake Bay Foundation commented that acetone is toxic to aquatic life, and that it has a potential to bioaccumulate, and therefore, it should not be removed from the EPCRA section 313 list of toxic chemicals. The commenter cites toxicity values of 10 milligrams/liter (mg/L) to *Daphnia magna*, and a median lethal concentration (LC<sub>50</sub>) for the clawed toad of 25 mg/L.

The toxicity values quoted by the commenter are within the range which are considered by EPA to be "moderately low." However, the majority of the available aquatic toxicity (LC<sub>50</sub>) values for acetone are greater than 100 mg/L. In fact, several studies reported LC<sub>50</sub> values for *Daphnia magna* of greater than 100 mg/L. Taken as a whole, the data indicate that acetone presents a low level of hazard to aquatic organisms. As to the statement that acetone has the potential to bioaccumulate, EPA disagrees. As stated in the proposed rule, acetone is readily biodegradable in aquatic systems. Its octanol/water coefficient (-0.24)

indicates a low potential for bioaccumulation, and its high water solubility indicates that acetone is not likely to biomagnify. The commenter did not supply any data which would lead EPA to change this assessment.

The Maine Greens comment that acetone is a known hazardous substance based on flammability, and the State and Territorial Air Pollution Program Administrators/Association of Local Pollution Control Officials comments that acetone should not be removed from the EPCRA section 313 list of toxic chemicals because delisting a flammable solvent will eliminate information needed by emergency response personnel regarding the true hazard presented by a given facility.

While EPA believes that the data collected under EPCRA section 313 may be of use to local response authorities in developing emergency response plans, it is not the primary focus of EPCRA section 313 as it is with EPCRA sections 302-312. Furthermore, flammability is not one of the criteria for listing a substance under EPCRA section 313.

#### B. Rationale for Delisting and Conclusions

EPA is granting the petition by deleting acetone from the EPCRA section 313 list. EPA believes that acetone does not meet the toxicity criteria of EPCRA section 313(d)(2)(A) because acetone exhibits acute toxicity only at levels that greatly exceed releases and resultant exposures. Specifically, acetone cannot reasonably be anticipated to cause " \* \* \* significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring releases."

EPA believes that acetone does not meet the toxicity criteria of EPCRA section 313(d)(2)(B) because acetone: (1) Cannot reasonably be anticipated to cause cancer or neurotoxicity and has not been shown to be mutagenic, and (2) cannot reasonably be anticipated to cause adverse developmental effects or other chronic effects except at relatively high dose levels.

EPA believes that acetone does not meet the toxicity criteria of EPCRA section 313(d)(2)(C) because acetone causes adverse environmental effects only at relatively high dose levels.

Based upon evaluation of the petition, available toxicity and exposure information, and public comment, EPA reaffirms its determination that acetone meets the EPCRA section 313(d)(3) criteria for deletion. Therefore, EPA is finalizing the deletion of acetone from

the list of chemicals subject to reporting under section 313 of EPCRA.

This petition does not request that any action be taken under any statutory provision other than EPCRA section 313, and today's rule should not be inferred as an action under any statutory provision other than EPCRA section 313. Each statute prescribes different standards for adding or deleting chemicals or pollutants from its respective list. Specifically, the deletion of acetone from the EPCRA section 313 list does not alter its regulatory status under other statutory provisions. Today's rule is based solely on the criteria in EPCRA section 313:

#### IV. Effective Date

This action is effective June 16, 1995. Thus the last year in which facilities had to file a Toxic Release Inventory (TRI) report for acetone was 1994, covering releases and other activities that occurred in 1993.

Section 313(d)(4) provides that "[a]ny revision" to the section 313 list of toxic chemicals shall take effect on a delayed basis. EPA interprets this delayed effective date provision to apply only to actions that add chemicals to the section 313 list. For deletions, EPA may, in its discretion, make such actions immediately effective. An immediate effective date, in these circumstances, is also consistent with 5 U.S.C. section 553(d)(1) because a deletion from the section 313 list relieves a regulatory restriction.

EPA believes that where the Agency has determined, as it has with acetone, that a chemical does not satisfy any of the criteria of section 313(d)(2)(A)-(C), no purpose is served by requiring facilities to collect data or file TRI reports for that chemical, or, therefore, by leaving that chemical on the section 313 list for any additional period of time. This construction of section 313(d)(4) is consistent with previous rules deleting chemicals from the section 313 list. For further discussion of the rationale for immediate effective dates for EPCRA section 313 delistings, see 59 FR 33205 June 28, 1994.

#### V. Rulemaking Record

The record supporting this rule is contained in the docket number OPPTS-400086A. All documents, including an index of the docket, are available in the TSCA Nonconfidential Information Center (NCIC), also known as the TSCA Public Docket Office, from noon to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA Public Docket Office is located at EPA Headquarters, Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

**VI. References**

(1) USEPA, OPPTS, HERD, HEB. Norris, Deborah O., "Summary of and Response to Health-Related Public Comments on Proposal to Remove Acetone from TRI," dated March 14, 1995.

(2) USEPA, OPPTS, EAB. Cinalli, C., "Exposure Report for Acetone," dated April 13, 1994.

(3) USEPA, OPPTS, EAB. Nold, A. and Cinalli, C., "Addendum to Exposure Report for Acetone," dated June 15, 1994.

**VII. Regulatory Assessment Requirements****A. Executive Order 12866**

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the Order defines a "significant regulatory action" as an action likely to lead to a rule (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically

significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

In accord with Executive Order 12866, EPA has prepared an economic analysis of this final rule. This final rule will reduce the number of reports submitted under EPCRA section 313 by 2,500 per year. EPA estimated that this will yield savings of \$7 million per year for industry and EPA. Pursuant to the terms of this Executive Order, EPA has determined that this final rule is not significant and therefore not subject to OMB review.

**B. Regulatory Flexibility Act**

Under the Regulatory Flexibility Act of 1980, EPA must conduct a small business analysis to determine whether a substantial number of small entities will be significantly affected. Because this final rule eliminates an existing requirement, it would result in cost savings to facilities, including small entities.

**C. Paperwork Reduction Act**

This final rule relieves facilities from having to collect information on the use

and releases of acetone. Therefore, there were no information collection requirements for OMB to review under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. This rule will reduce reporting burden by approximately 131,000 hours per year."

**List of Subjects in 40 CFR Part 372**

Environmental protection, Chemicals, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: June 9, 1995.

Lynn R. Goldman,  
Assistant Administrator for Prevention,  
Pesticides and Toxic Substances.

Therefore, 40 CFR part 372 is amended as follows:

1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11013 and 11028.

**§ 372.65 [Amended]**

2. Section 372.65(a) and (b) are amended by removing the entire entry for acetone under paragraph (a) and removing the entire CAS No. entry for 67-64-1 under paragraph (b).

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